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HOSPITAL VARIATION IN SPHINCTER PRESERVATION FOR ELDERLY RECTAL CANCER PATIENTS

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Abstract

Purpose—To evaluate hospital variation in the use of low anterior resection (LAR), local excision (LE) and abdominoperineal resection (APR) in the treatment of rectal cancer in elderly patients.

Methods—Using SEER-Medicare linked data, we identified 4,959 stage I–III rectal cancer patients over age 65 diagnosed from 2000–2005 who underwent operative intervention at one of 370 hospitals. We evaluated the distribution of hospital-specific procedure rates and used generalized mixed models with random hospital effects to examine the influence of patient characteristics and hospital on operation type, using APR as a reference.

Results—The median hospital performed APR on 33% of elderly rectal cancer patients. Hospital was a stronger predictor of LAR receipt than any patient characteristic, explaining 32% of procedure choice, but not a strong predictor of LE, explaining only 3.8%. Receipt of LE was

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primarily related to tumor size and tumor stage, which, combined, explained 31% of procedure variation.

Conclusions—Receipt of local excision is primarily determined by patient characteristics. In contrast, the hospital where surgery is performed significantly influences whether a patient undergoes an LAR or APR. Understanding the factors that cause this institutional variation is crucial to ensuring equitable availability of sphincter preservation.

INTRODUCTION

Reported rates of sphincter preserving surgery (SPS) for rectal cancer in the US range from 26.9% to 54.3% (1, 2). Preservation of continence is an important goal, but will not be technically feasible in all patients. While reported rates have increased over time (1) with improved surgical technique (3, 4) and preoperative imaging modalities (5), a large amount of institutional variability remains (1, 6). A recent evaluation by Temple et al. revealed overall SPS rates in seven National Comprehensive Cancer Network (NCCN) institutions to be 77% (6). However, even amongst these structurally similar hospitals there was a wide range in the rate of SPS (38–85%) (6). Some of this variability was attributed to discordant evidence regarding resection margin (7–9) or to institution specific culture and views regarding the functional outcomes of low anastomoses. Additional studies of population-based samples have illustrated that decreased SPS rates have been associated with race (1, 10–12), low volume hospitals (13), and lower socioeconomic status (1). More investigation is necessary to understand the role of hospital-level factors in determining likelihood of sphincter preservation for rectal cancer patients.

Traditionally, SPS has been defined in research studies as low anterior resection (LAR) or all patients not receiving abdominoperineal resection (APR) (2, 6, 12, 14). Advances in local excision (LE), such as transanal endoscopic microsurgery (TEMs) provide a different approach to sphincter sparing surgery for in situ tumors (Tis) and low grade tumors limited to the submucosa (T1) with similar outcomes to radical resection (15–18). Additionally, a prior SEER evaluation showed that increasing age is significantly correlated with greater rates of local excision (19). Therefore, we chose to evaluate both LAR and LE to examine rates of sphincter preservation for select eligible patients.

To date, one study (20) has examined the influence of both patient and hospital characteristics on sphincter preservation rates among a national sample but did not control for tumor characteristics or neoadjuvant therapy. Our study is the first to evaluate the contribution of patient, hospital and tumor characteristics on rates of sphincter preservation on a national sample of rectal cancer patients over 65 years old across multiple institutions.

METHODS

Data Sources

Data from the Surveillance, Epidemiology and End Results (SEER) registries and Medicare claims have been linked to allow for longitudinal analysis of cancer and treatment outcomes. The 17 SEER registries, sponsored by the National Cancer Institute (NCI), represent approximately 28% of the US population and 94% of SEER patients aged 65 or over have

had their records linked to Medicare claims. Additionally, these claims are linked to census (2000) tract and zip code level data to provide further demographic information.

Study Sample

Our study cohort included all Medicare-eligible patients age 65 and older, diagnosed in SEER regions with primary rectal cancer between 2000 and 2005. We specifically selected for adenocarcinoma (SEER histology codes 8010, 8140, 8144, 8210–11, 8220–21, 8260–63, 8470, 8480–81, and 8490) and American Joint Committee on Cancer (AJCC) stage I–III disease and excluded patients with stage IV. Patients who were enrolled in health care management organizations (HMOs) or were not in both Medicare part A and part B continuously during the study period were excluded, as were patients with a diagnosis noted exclusively on death certificates or autopsy, and those patients where the month of diagnosis was unknown. To best limit the analysis to rectal cancer where sphincter preservation was a concern, cancers located at the rectosigmoid junction were excluded. For the local excision analysis (APR vs. LE), the cohort was limited to those patients with AJCC stage I disease.

We searched both part A and part B Medicare claims files for rectal cancer operations performed from 30 days prior to 1 year post-diagnosis. Operations were categorized according to the International Classification of Diseases Clinical Modification (ICD-9-CM) and Current Procedural Technology (CPT) classification systems. Only patients who had standard resections for rectal cancer were included: APR (ICD-9-CM 48.5, CPT 45110, 45395), LAR (ICD-9-CM 48.6x, CPT 45111–13, 45119, 45397) and LE (ICD-9-CM 48.35, CPT 45160, 45170). If patients had both a local excision code and a subsequent LAR or APR code they were analyzed in the latter category. Finally, to increase stability of our results, analysis was limited to only those patients who received care from institutions performing at least 5 procedures in our cohort. Our final cohort included 4,959 patients from 370 hospitals.

Covariates

Patient demographics, median household income, proportion of those with a college education and tumor-related variables (grade, tumor stage, lymph node status, and size) were obtained from SEER registry data. Comorbidities were captured in the year prior to diagnosis from the outpatient, inpatient and carrier claims using the Deyo modification (21) of the Charlson comorbidity index (22), applied to both inpatient and outpatient claims as suggested by Klabunde (23). Variables were categorized as in Table 1a and 1b for univariate analysis but race (white, black, other), age (65–79, ≥80), and comorbidity score (0, ≥1) were collapsed for multivariable analysis.

We used the unique American Hospital Association (AHA) hospital identification number to link each patient with the hospital characteristics available in the Medicare hospital file (<http://healthservices.cancer.gov/seermedicare/privacy/Hospital.filedescription.pdf>). These hospital characteristics included urban location, designation as a NCI cancer center, medical school affiliation, membership in an oncology group and hospital ownership. The Center for Medicare and Medicaid Services (CMS) region of the treating hospital was used to examine

geographic variations for Northeast (Boston, New York, Philadelphia), Midwest (Chicago, Kansas City), South (Atlanta, Dallas) and West (Denver, San Francisco, Seattle).

Statistical Analysis

Hospital-specific procedure rates were calculated for APR, LAR and LE. Temporal relationships in procedure-specific rates were analyzed using Mantel-Haenszel chi-square test for trend, accounting for clustering of patients within hospital. In order to evaluate the association between procedure performed (APR, LAR, LE) and *a priori* specified patient- and hospital characteristics, Rao-Scott chi-square test for categorical variables (such as tumor stage) and generalized estimating equations chi-square test for continuous variables (such as patient age), were used to account for clustering of patients within hospital.

Multivariable patient-level models included these *a priori* potential explanatory patient and hospital characteristics and all tumor variables. Additionally, all other clinical, demographic and hospital variables with a p value <0.10 on univariate analysis were considered for inclusion.

In multivariable analyses, we controlled for the effects of clustering within hospital using generalized linear mixed models to fit a logistic regression with hospital as a random effect. We then added fixed hospital characteristics to this mixed model (with a random hospital effect) to determine the amount of the hospital-to-hospital variability that can be attributed to known hospital characteristics. Two models were evaluated to assess the influence of characteristics on sphincter preservation, APR vs. LAR and APR vs. LE. In order to determine the comparative effect of each institution and patient level variable, the absolute and percent change in logistic regression pseudo- R^2 was determined. The pseudo- R^2 for our 'full' model included hospital random effect and significant patient-level characteristics (covariates). The percent change in R^2 (% R^2) for the full model measured the total variability in procedure rates across hospitals. The hospital random effect allows for estimation of the maximal variability in procedure rates explained by all hospital characteristics. C-statistics were used to evaluate the fit of our 'full' APR vs. LAR and APR vs. LE predictive models.

Several methods were examined to assess the best way to account for missing data in our cohort. Weighted estimating equations (using all data) and a complete case analysis excluding all patients with any missing data were evaluated. The results were similar, so for simplicity, we present the complete case analysis. Univariate analysis was performed using the 4,959 patient cohort, but for our final multivariable analysis, patients with missing data were excluded, leaving a total of 2,373 in the LAR vs. APR analysis. Additionally, since local excision is not indicated for all patients, the LE vs. APR comparison was further limited to AJCC stage I patients, resulting in 565 patients available for final analysis. All patients who underwent local excision were included in Table 1 to illustrate the distribution of care provided to rectal cancer patients.

The Dana-Farber/Harvard Cancer Center Office for Human Research Studies approved our study protocol after expedited review. All statistical analyses were performed with SAS

Version 9.2 (SAS Institute, Cary, NC). All p-values were two-sided, and were considered statistically significant if $p < 0.05$.

RESULTS

Time Trend

We examined the time trends in sphincter preservation in all available patients from 1991–2005 ($n=9,716$). Figure 1 illustrates the significant decrease in APR rates 48% to 29% ($p<0.001$) as LAR rates increased [31% to 50% ($p<0.001$)] and LE 21% ($p=0.04$) remained unchanged. Given the significant change in both LAR and APR rates over time, we limited our remaining analyses to 2000–2005 to obtain a more accurate representation of current practice patterns.

Patient and Hospital Characteristics

A total of 4,959 patients diagnosed with stage I–III rectal cancer from 2000–2005 underwent surgical resection at one of 370 hospitals. The majority of patients were Caucasian (90.4%), non-Hispanic (92.6%), with no co-morbidities (68.6%). Additional cohort and hospital characteristics are shown in Table 1a and 1b. Nearly 70% of patients underwent a sphincter sparing operation, 2434/4959 (49%) LAR and 960/4959 (19%) LE. Univariate analyses revealed significant differences in the demographics, clinical factors and hospital characteristics for patients receiving LAR or LE as compared to APR as shown in Table 1a and 1b.

Hospital Variability

Hospital rates of rectal procedures stratified by operation were calculated for all 370 institutions. There was wide variability in the hospital rates of APR, LAR and LE. 5.7% (21/370) of hospitals performed LAR on greater than 80% of their patients. 2.7% of hospitals performed no LAR operations. The median hospital performed APR on 33%, LAR on 48%, and LE on 17% of rectal cancer patients.

In multivariable analysis accounting for clustering by hospital, Tables 2 & 3 describe the significant predictors of procedure rate variation between hospitals and the percent contribution each make to the overall variation measured as % change in R^2 .

Receipt of neoadjuvant therapy (18.9% of variation), tumor size (25.8%) and tumor stage (11.8%) were all significant determinants of LAR. When combined, all patient characteristics explained 73% of the variation in rates of LAR vs. APR between hospitals (c statistic of 0.76) (Table 2). Receipt of LE was strongly associated with both clinical variables (tumor size – 21.8%, stage – 10.2% and receipt of neoadjuvant therapy – 8.5%) and patient demographics (income – 4.6% and age – 2.6%) which, when combined, explained 87% of procedure variation (c-statistic =0.93) (Table 3).

Hospital was a stronger predictor of LAR receipt than any patient characteristic alone, explaining 32.7% of procedure choice, but not a strong predictor of LE, explaining only 3.8% (Tables 2 & 3). To evaluate the contribution of available hospital structural characteristics to overall institutional variation, we added fixed institutional effects

individually to the model. Urban hospital location was the most significant hospital characteristic in determining receipt of LAR, yet accounted for only 2% of procedure variation. Membership in an oncology group as identified in the SEER-Medicare Hospital file was a significant characteristic in determining receipt of both LAR and local excision, explaining 4% and 2% of the total influence of the hospital. All other hospital characteristics reported in Table 1b were not significant on multivariable analysis.

DISCUSSION

The primary goal of an operation for rectal cancer is to cure cancer and, where possible, preserve continence. Nearly 70% of elderly rectal cancer patients were shown in this study to receive sphincter-preserving operations – 49% LAR and 19% LE. This compares favorably with other published rates (2, 6, 14, 20, 24).

The decision to perform sphincter preservation, in particular LAR, in the elderly is a complicated one. Studies have demonstrated that stage appropriate surgery in the elderly can be performed with low risk of death or morbidity (25–27) and when matched stage for stage APR and LAR have similar long term oncologic outcomes (28). Additionally, when given the choice most patients would prefer sphincter preservation to an APR (29). However, sphincter preservation is not benign, intractable incontinence rates have been as high as 27% (30) that can be more severe in the elderly who can have worse baseline incontinence (31–32). Furthermore, advancing age can increase post-operative anastomotic leak rates (33) which can be mitigated by proximal diversion (34–35) but often stomas are not reversed in the elderly (36).

Therefore, it is not surprising that wide variation exists in sphincter preservation among the elderly but our data suggest that the institution where patients seek care may significantly influence their operative intervention. Specifically, after controlling for clinical stage and patient demographics, the hospital where a patient underwent their rectal cancer operation was more significant than any available clinical variable in determining whether they underwent LAR or APR.

The significant influence of hospital characteristics on complex procedure rates is not a novel finding, however, our study is the first to quantify the overall influence of a hospital on sphincter preservation rates in the elderly. Prior evaluations of institutional variation have found that nurse to patient ratios, hospital size, access to advanced medical technology, volume and teaching status can significantly influence surgical treatment and outcomes (26–31). In evaluation of rectal cancer, rates of sphincter preservation have been found to vary by gender (1, 20) race (1, 10–12), age (1, 19–20) and socioeconomic status (1); with greater rates found in high volume (13, 2, 44, 45) and urban hospitals (20).

Given documented limitations in measuring procedural volume in SEER-Medicare (47–49) we did not include this as an institutional characteristic in this study. However, volume is a proxy for and associated with other hospital characteristics that were investigated. Our results corroborate the significant influence of urban hospital location on sphincter preservation rates (LAR vs. APR) as found by Paquette et al in their evaluation of the

National Inpatient Sample. Their significant relationship remained even after controlling for hospital procedure volume. They conjectured that while volume contributed some to sphincter preservation in urban centers, existing referral patterns might account for the remaining influence. Determining the exact significance of urban location will require more detailed hospital information in future studies.

Unique to our study, we found that participation in a cancer cooperative group was significantly associated with increased rates of LAR. The cooperative groups conduct prospective clinical trials, to evaluate all aspects of cancer treatment. While these groups have broad membership including academic centers, community hospitals, and teaching affiliate hospitals, membership is predicated on their ability to enroll patients in and conduct these clinical trials. Often this requires significant infrastructure and resources. Oncology group membership has also been associated with improved guideline adherence in colorectal cancer patients with respect to lymph node evaluation (51) and increased use of chemotherapy (52).

In contrast to our LAR findings, the hospital played a much smaller role in determining variation in local excision rates. Both tumor and patient characteristics overshadowed the influence of institution. These results suggest that local excision decisions may be more individualized to the patient, their preferences and the clinical characteristics of their cancer. Furthermore, it may represent less ambiguity of indications for local excision (53–54). Or it may reflect that local excision is often a less complex procedure, which, as a consequence, is more widely available. While we were not able to account for differences in patient preference in our current study, it is encouraging that our results for local excision have face validity based on available clinical evidence – the primary determinant of eligibility for local excision with adequate oncologic outcome is tumor size and stage (25).

Our study has several limitations. It is retrospective, relies on claims data and may only be applicable to the elderly population. SEER-Medicare lacks any information about the distance from the tumor to the anal verge, which has been shown to be significantly associated with sphincter preservation rates (6, 13). In addition, our dataset has no information on preoperative continence or predicted postoperative function that would influence provider's decision to perform or patient's willingness to undergo sphincter preservation. However, though having distance to the anal verge and functional measurements would augment our results, both Temple et al. and Meyerhart et al. found that hospital level characteristics remained significant after controlling for distance to the anal verge and that variation across institutions remained. Finally, we were not able to account for patient preference, which some studies suggest can influence sphincter preservation rates (36). It is possible that patients who prefer this approach could elect for surgical intervention at hospitals known to have higher rates of sphincter preservation, which has been shown in other complex procedures (57), thereby magnifying our results.

Our results confirm the increasing rates of sphincter preservation across the country (1, 20) and highlight the broad distribution of LAR, APR and LE rates across institutions. While clinical and patient characteristics play the greatest role in determining local excision rates, the hospital was the strongest examined predictor of low anterior resection rate. These

results add to the growing body of literature documenting variation in rates of surgical procedures based on institutional factors (26–31). Although we found that both urban location and oncology group membership can significantly influence sphincter preservation rates, these represent only a small proportion of the variation in rates across hospitals. The majority of our hospital variation in LAR vs. APR remains unexplained by our discrete variables. The unexplained variation may reflect other hospital structural and organizational characteristics not measureable in SEER-Medicare (payer mix (32) or physician subspecialty training (33, 34)) or it may represent institutional culture or provider preferences depending on interpretation of literature, training, knowledge, judgment or technical skill, which are more difficult to evaluate. Identifying the specific causes of hospital influence will likely require a more extensive source of hospital characteristics linked to patient outcomes and/or administration of instruments (35) that assess cultural attitudes that facilitate or inhibit sphincter preservation. A better understanding of the etiology of this variation will allow targeted interventions to ensure that SPS is more equitably available for elderly rectal cancer patients.

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SYNOPSIS

A SEER-Medicare linked cohort of 4,959 patients with stage I–III rectal cancer were evaluated for temporal and institutional variations in rates of sphincter preserving surgical treatment. It was found that hospital was the strongest examined predictor of low anterior resection rate, suggesting that specific hospital factors, yet to be delineated, drive institutional rates of this sphincter preserving procedure.

Figure 1. Surgical Procedure Time Trend from 1991 to 2005
 Separate lines depict yearly proportion of APR, LAR or Local Excision

Table 1a

Patient Characteristics –grouped by procedure: Abdominoperineal Resection (APR), Low Anterior Resection (LAR), and Local Excision (LE) respectively

PATIENT CHARACTERISTICS	APR (referent)	LAR	p value ^a	LE ^d	p value ^b
N (%)	1565 (31.6)	2434 (49.1)		960 (19.3)	
Median Age at Diagnosis (years)	75.5	75.2	0.45	77.7	<.001
Female	698 (45%)	1137 (47%)	0.17	540 (56%)	<.001
Race/Ethnicity					
Caucasian	1424 (91%)	2165 (89%)	0.04	885 (92%)	0.09
Black	72 (5%)	110 (5%)		32 (3%)	
Asian/Pacific Islander/Other	69 (4%)	159 (7%)		43 (4%)	
Hispanic	114 (7%)	152 (6%)	0.21	53 (6%)	0.10
Married	856 (55%)	1427 (59%)	0.02	483 (50%)	0.03
Median Percent Some College	27.9%	27.4%	0.09	27.6%	0.66
Household Median Income	\$36,371	\$38,766	<.001	\$39,452	<.001
Charlson Comorbidity Score					
0	1065 (68%)	1628 (67%)	0.18	603 (63%)	<.001
1	350 (22%)	529 (22%)		216 (23%)	
2+	150 (10%)	277 (11%)		141 (15%)	
AJCC Stage^d					
0	29 (2%)	116 (5%)	<.001	207 (22%)	<.001
I	370 (24%)	784 (32%)		505 (53%)	
II	471 (30%)	660 (27%)		72 (8%)	
III	572 (37%)	748 (31%)		11 (1%)	
Unknown	123 (8%)	126 (5%)		165 (17%)	
Tumor Grade					
Well Differentiated	112 (7%)	186 (8%)	0.11	125 (13%)	<.001
Moderately Differentiated	1063 (68%)	1686 (69%)		500 (52%)	
Poorly Differentiated	268 (17%)	318 (13%)		103 (11%)	
Undifferentiated/Anaplastic	13 (1%)	21 (1%)		^c	
Not Determined	109 (7%)	223 (9%)		232 (24%)	

PATIENT CHARACTERISTICS	APR (referent)	LAR	p value ^a	LE ^d	p value ^b
Neoadjuvant Chemotherapy	467 (30%)	469 (19%)	<.001	32 (3%)	<.001
Neoadjuvant Radiation Therapy	591 (38%)	605 (25%)	<.001	49 (5%)	<.001

^a p-value for bivariate comparison of LARv. APR

^b p-value for bivariate comparison of LE v. APR

^c Poorly differentiated and undifferentiated tumor grades have been combined to protect patient confidentiality per data use agreement

^d Nodal Stage. Tumor Stage significant on univariate analysis substituted for AJCC Stage

Table 1b

Hospital Characteristics –grouped by procedure: Abdominoperineal Resection (APR), Low Anterior Resection (LAR), and Local Excision (LE) respectively

HOSPITAL CHARACTERISTICS	APR (referent)	LAR	p value ^a	LE ^d	p value ^b
N (%)	1565 (316)	2434 (49.1)		960 (19.3)	
Urban Location	1422 (91%)	2299 (94%)	<.001	882 (92%)	0.61
NCI Center (Comprehensive)	78 (5%)	125 (5%)	0.90	52 (5%)	0.63
Oncology Group (Any)	1193 (76%)	1955 (80%)	0.03	790 (82%)	0.01
Med School Affiliation					
Major/Limited/Graduate	775 (50%)	1242 (51%)	0.07	520 (54%)	0.08
None	790 (50%)	1192 (49%)		440 (46%)	
Ownership					
Nonprofit	1284 (82%)	2095 (86%)	0.05	824 (86%)	0.02
Proprietary	138 (9%)	167 (7%)		46 (5%)	
Governmental	143 (9%)	172 (7%)		90 (9%)	
CMS Region					
Northeast	377 (24%)	649 (27%)	0.05	309 (32%)	0.002
Midwest	290 (19%)	345 (14%)		132 (14%)	
South	331 (21%)	482 (20%)		174 (18%)	
West	567 (36%)	958 (39%)		345 (36%)	

^a p-value for bivariate comparison of LAR v. APR

^b p-value for bivariate comparison or LE v. APR

Table 2

Predictors of Hospital Variation in Rates of LAR vs APR on Multivariable Analysis– Amount of contribution to variation across hospitals illustrated by % change in R^2

LAR vs APR Model		$R^2 = 0.058$
		C statistic = 0.756
		N = 2373
Variable	% of Variation Explained (% R^2)	
Hospital	32.1%	
All Patient Characteristics	73.2%	
Tumor Size	25.8%	
Neo-adjuvant Therapy	18.9%	
Tumor Stage	11.8%	

Baseline model included random hospital effects and significant patient characteristics

Table 3

Predictors of Hospital Variation in Rates of Local Excision vs APR on Multivariate Analysis –Amount of contribution to variation across hospitals illustrated by % change in R^2

Local Excision vs APR Model		$R^2 = 0.454$
		C stat = 0.931
		N = 565
Variable	% of Variation Explained (% R^2)	
Hospital	3.8%	
All Patient Characteristics	87.3%	
Tumor Size	21.8%	
Neo-adjuvant Therapy	8.5%	
Tumor Stage	10.2%	
Year Diagnosed	5.4%	
Median Income by Census Tract	4.6%	
Age	2.6%	

Baseline model included random hospital effects and significant patient characteristics